General

Guideline Title

ACR Appropriateness Criteria® radiologic management of iliofemoral venous thrombosis.

Bibliographic Source(s)

Hohenwalter EJ, Ray CE Jr, Lorenz JM, Darcy MD, Fidelman N, Gervais DA, Gipson MG, Kapoor BS, Kolbeck KJ, Kouri BE, Mansour MA, Marshalleck FE, Nair AV, Rochon PJ, Shaw CM, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of iliofemoral venous thrombosis. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 6 p. [29 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Radiologic Management of Iliofemoral Venous Thrombosis

Variant 1: First episode of iliofemoral deep vein thrombosis (DVT). Symptoms present for <14 days, otherwise healthy.

Treatment/Procedure	Rating	Comments
Anticoagulation alone	5	
Catheter directed thrombolysis (CDT)	8	
Surgical thrombectomy	3	Perform this procedure if a contraindication to anticoagulation or thrombolytics exists.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 2: Iliofemoral deep vein thrombosis (DVT) and symptoms ≤10 days. Computed tomography scan demonstrates potential for May-Thurner syndrome.

Treatment/Procedure	Rating	Comments
Anticoagulation alone	3	Perform this procedure if patient is not a candidate for thrombolysis.
Catheter directed thrombolysis (CDT) with evaluation and potential stent placement	8	
Surgical thrombectomy and repair of iliac vein	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 3: Iliofemoral deep vein thrombosis (DVT) and limb-threatening ischemia (phlegmasia cerulea dolens).

Treatment/Procedure	Rating	Comments
Anticoagulation alone	3	
Catheter directed thrombolysis (CDT)	8	
Surgical thrombectomy	6	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 4: Iliofemoral deep vein thrombosis (DVT) with minimal symptoms. DVT diagnosed one week ago.

Treatment/Procedure	Rating	Comments
Anticoagulation alone	7	Use of anticoagulation versus thrombolysis depends on general clinical condition of patient.
Catheter directed thrombolysis (CDT)	7	Use of anticoagulation versus thrombolysis depends on general clinical condition of patient. Perform this procedure in younger patients to avoid the risk of post-thrombotic syndrome.
Surgical thrombectomy	2	
Systemic thrombolysis	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Summary of Literature Review

Introduction/Background

Venous thromboembolism (VTE) consists of both deep vein thrombosis (DVT) and pulmonary embolism (PE) and is associated with significant morbidity. The incidence of VTE is approximately 100/100,000 population each year in the United States. The risk proportionately increases with age and ranges from 5/100,000 for people <15 years old to 500/100,000 for people >80 years old. The major risk factors associated with VTE were described by Virchow: hypercoagulability, endothelial injury, and stasis. The most frequent risk factors include surgery, trauma, hip fracture, prolonged immobility, and several inherited and acquired hematological conditions. Full-dose anticoagulation is the standard therapy for VTE, both for the acute and the long-term phase. The latest guidelines from the American College of Chest Physicians recommend treatment with a full dose of unfractionated heparin, low-molecular-weight-heparin, fondaparinux, vitamin K antagonist, or thrombolysis for most patients with objectively confirmed VTE. Although anticoagulation effectively prevents thrombus extension, PE, death, and recurrence, many patients develop venous dysfunction resulting in post-thrombotic syndrome (PTS). This syndrome is characterized by pain, swelling, a heavy sensation, edema, pigmentation, and ulceration in severe cases. The most severe PTS morbidity occurs in patients with iliofemoral DVT.

Initial Treatment of Acute DVT of the Lower Extremity

Anticoagulation is the standard initial therapy for acute DVT. The main objective in the initial treatment of DVT is to prevent thrombus extension

and recurrence. The evidence for the need for anticoagulation in patients with acute DVT is based on studies performed several years ago. The first trial comparing anticoagulation versus no anticoagulation in patients with VTE was published in 1960. This study showed that treatment with heparin and a vitamin K antagonist markedly reduced recurrent PE and mortality. Other studies have shown reduced mortality in patients when heparin is used to treat VTE compared to patients who did not receive anticoagulation. In addition, a randomized controlled study reported a three-fold increase in the rate of recurrent VTE in patients treated with a vitamin K antagonist alone versus those initially treated with heparin and converted to a vitamin K antagonist. In regards to duration of initial heparin therapy, 2 randomized clinical trials for patients with proximal DVT reported that intravenous unfractionated heparin administered for 5 to 7 days is as effective as 10 to 14 days, providing that it is followed by adequate long-term anticoagulant therapy. This shorter duration of heparin therapy may also help reduce the incidence of heparin-induced thrombocytopenia. The currently recommended approach is to start both heparin and a vitamin K antagonist at the time of diagnosis and to discontinue heparin after 5 days, provided the international normalized ratio is ≥2.0 for at least 24 hours. Multiple anticoagulation regimens are recommended to treat VTE and are beyond the scope of this document.

Early Thrombus Removal

Although anticoagulation effectively prevents thrombus extension, PE, death, and recurrence, many patients develop venous dysfunction resulting in PTS. PTS occurs in 20% to 50% of patients after acute DVT, and leg ulceration can occur in as many as 10% of patients. PTS can lead to disability and reduced quality of life with important clinical and public health implications. Oral anticoagulation reduces thrombus propagation but does not effectively produce clot lysis, which can result in incomplete prevention of PTS. Patients with iliofemoral DVT are the subset of patients with the largest thrombus burden and the highest risk for post-thrombotic morbidity; up to 75% have chronic painful edema, and 40% have venous claudication when treated with anticoagulant therapy alone. Treatments that actively remove thrombus have the potential to reduce the risk of developing PTS as well as relieve the immediate symptoms of DVT. The effectiveness of systemic thrombolysis to achieve early clot lysis has been investigated in a number of trials that found it to be associated with high rates of bleeding complications with relatively modest rates of thrombus clearance. The rationale for catheter-directed thrombolysis (CDT) is that rapid lysis is achieved with lower doses of thrombolytic agent, resulting in fewer serious bleeding complications. In the National Venous Registry, patients treated with short-term DVT (<10 days) had better outcomes than those with older clots who underwent correction of underlying venous lesions after successful thrombolysis. The addition of mechanical thrombus fragmentation during CDT is commonly used as part of the procedure. This is termed pharmacomechanical thrombolysis. Retrospective analyses comparing CDT alone versus pharmacomechanical thrombolysis suggest they are associated with similar rates of successful thrombolysis and major bleeding; however, pharmacomechanical thrombolysis was associated with shorter treatment times, shorter intensive care unit (ICU)/hospital stays, and reduced costs. Furthermore, the CaVenT study was a prospective randomized controlled trial that evaluated the effects of additional CDT in patients with acute DVT in regards to PTS. This study demonstrated a clinically significant reduction of PTS after additional CDT was performed compared with conventional treatment alone.

Indications for Thrombolytic Therapy

Although a definitive multicenter randomized controlled trial has yet to be completed, the available evidence favors use of CDT and pharmacomechanical thrombolysis in DVT patients with clinically severe manifestations of DVT. These severe manifestations include phlegmasia cerulea dolens (PCD), acute inferior vena cava (IVC) thrombosis, and rapid thrombus extension despite anticoagulation as well as anatomically extensive DVT that includes the common femoral and/or iliac vein since this degree of thrombus carries a higher risk of recurrent DVT and PTS.

Acute Iliofemoral Deep Vein Thrombosis

Recommendations for early thrombus removal are based on balancing the benefits of preventing PTS versus the risks of therapy (e.g., bleeding, recurrent DVT). A recent meta-analysis evaluating treatment options for iliofemoral DVT revealed a statistically significant reduction in the risk of PTS and venous obstruction in patients treated with CDT versus those treated with anticoagulation alone. The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) have also recently published joint clinical practice guidelines for early thrombus removal in patients with acute iliofemoral DVT. They recommend early thrombus removal in patients who present with acute iliofemoral DVT, symptoms <14 days, low risk of bleeding, and a reasonable life expectancy. The 14 day cut off is somewhat arbitrary, however among the patients enrolled in the National Venous Registry, patients with DVT and symptoms >10 days had significantly worse outcomes than patients with symptoms <10 days. Other guidelines have suggested that DVT associated with symptoms ≤14 days should be considered acute, and a recently published randomized trial included patients with symptoms <21 days.

Phlegmasia Cerulea Dolens

PCD is characterized by massive swelling, cyanosis, and pain resulting from extensive thrombosis of the iliofemoral venous system. Venous gangrene occurs when extensive thrombus leads to venous hypertension and small arterial collapse due to the surrounding tissue pressure. Calf compartment pressures of ≥50 mm Hg have been documented in association with PCD. Since this is a potentially life- and limb-threatening condition, the benefits of early thrombus removal outweigh the risks in this clinical scenario.

May-Thurner Syndrome

May-Thurner syndrome is characterized by compression of the left common iliac vein between the right common iliac artery and vertebrae. This compression is thought to induce endothelial irritation and lead to left lower extremity DVT. The importance of underlying iliac vein lesions cannot be fully appreciated in patients treated with anticoagulation alone. As early thrombus removal techniques have advanced, it has become clear that underlying iliac vein lesions, in this case compression, may contribute to many cases of iliofemoral DVT. In the National Venous Registry, 33% of limbs required treatment with stents, and the 1-year patency (74%) was significantly better in those limbs compared to the limbs without stent placement (53%; P<.001).

Pharmacomechanical Thrombolysis Devices

There are 2 most commonly used devices for pharmacomechanical thrombolysis. The first is a device that uses high-velocity saline jets for the percutaneous break-up and removal of thrombus. This device also has a "power pulse" function allowing additional thrombolytic penetration into the thrombus. The second device utilizes a macerating wire to break up the thrombus while thrombolytic. It consists of a catheter for infusion of fluids into a treatment area isolated between 2 occluding balloons. These devices are currently incorporated in the ATTRACT study (Acute Venous Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis), which is a randomized controlled trial evaluating subsequent PTS in patients with acute DVT treated with pharmacomechanical thrombolysis plus standard anticoagulation versus anticoagulation alone in the treatment of acute DVT.

Surgical Thrombectomy

Venous thrombectomy has been compared with anticoagulation in the past and has been demonstrated to potentially preserve the venous function. One meta-analysis comparing the efficacy of anticoagulation, surgical thrombectomy, and CDT was recently published and found that both surgical thrombectomy and CDT decrease the incidence of PTS. The SVS/AVF guidelines recommend surgical venous thrombectomy in patients who are candidates for anticoagulation but in whom thrombolytic therapy is contraindicated. For patients who are candidates for either approach, a higher value is placed on avoiding the more invasive procedure and the potential surgical complications.

Patient Selection

Patient selection for CDT is individualized. Important considerations include the patient's bleeding risk profile, life expectancy, anticipated activity level, and their willingness to undergo a procedure that may require an overnight hospital stay. Successful thrombolysis is most likely achieved in patients with recently formed thrombus and symptom duration less than 10 to 14 days. Patients who have short life expectancy, do not ambulate, have had recent surgery or trauma, have intracranial lesions, and have thrombocytopenia are poor candidates.

Compression Stockings

The role of compression stockings in the management of chronic venous disorders has been well established. Compression stockings improve the calf muscle pump function and reduce edema. The use of graded elastic compression stockings decreases by 50% the incidence of objectively defined PTS after a first episode of proximal DVT treated with conventional anticoagulation. For this reason, the SVS/AVF guidelines recommend 30–40 mm Hg compression stockings for 2 years following early thrombus removal.

Summary

- VTE is associated with significant morbidity.
- The main objectives of anticoagulation are to prevent thrombus extension and early and late recurrence of VTE.
- Conventional anticoagulation alone does not prevent post-thrombotic syndrome.
- Catheter-directed thrombolysis and pharmacomechanical thrombolysis may decrease the incidence in PTS in patients with acute iliofemoral DVT with proper patient selection.
- The ATTRACT trial is a randomized controlled trial currently underway and will likely provide further evidence regarding the clinical utility of pharmacomechanical thrombolysis for patients with acute iliofemoral DVT.

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Iliofemoral venous thrombosis

Guideline Category

Management

Treatment

Clinical Specialty

Critical Care

Emergency Medicine

Family Practice

Internal Medicine

Radiology

Surgery

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of radiologic management of iliofemoral venous thrombosis

Target Population

Patients with iliofemoral venous thrombosis

Interventions and Practices Considered

1. Anticoagulation alone
2. Catheter directed thrombolysis (CDT)
3. CDT with evaluation and potential stent placement
4. Surgical thrombectomy
5. Surgical thrombectomy and repair of iliac vein
6. Systemic thrombolysis

Major Outcomes Considered

Complications of interventional procedures

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff will search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid, but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distribute surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for management of iliofemoral venous thrombosis

Potential Harms

- The effectiveness of systemic thrombolysis to achieve early clot lysis has been investigated in a number of trials that found it to be associated with high rates of bleeding complications with relatively modest rates of thrombus clearance.
- Retrospective analyses comparing catheter directed thrombolysis (CDT) alone versus pharmacomechanical thrombolysis suggest they are associated with similar rates of successful thrombolysis and major bleeding.
- Although anticoagulation effectively prevents thrombus extension, pulmonary embolism (PE), death, and recurrence, many patients develop venous dysfunction resulting in post-thrombotic syndrome (PTS). This syndrome is characterized by pain, swelling, a heavy sensation, edema, pigmentation, and ulceration in severe cases. The most severe PTS morbidity occurs in patients with iliofemoral deep vein thrombosis (DVT).
- Patients with iliofemoral DVT are the subset of patients with the largest thrombus burden and the highest risk for postthrombotic morbidity; up to 75% have chronic painful edema, and 40% have venous claudication when treated with anticoagulant therapy alone.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection

of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Hohenwalter EJ, Ray CE Jr, Lorenz JM, Darcy MD, Fidelman N, Gervais DA, Gipson MG, Kapoor BS, Kolbeck KJ, Kouri BE, Mansour MA, Marshalleck FE, Nair AV, Rochon PJ, Shaw CM, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of iliofemoral venous thrombosis. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 6 p. [29 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Interventional Radiology

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – therapeutic studies. Reston (VA): American College of Radiology; 2013 Nov. 4 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria® radiologic management of iliofemoral venous thrombosis. Evidence table. Reston (VA): American College of Radiology; 2013. 17 p. Electronic copies: Available from the ACR Web site .

Patient Resources

None available

NGC Status

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